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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,229	03/27/2001	Alastair V. Ferguson	1669.0040001/SRL/BLS	8063

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,229	FERGUSON ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1-7 and 18-20 are pending in the instant application.

Claims 1-7 and 18-20 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on September 8, 2003 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 103

5. Claims 1-7 and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Stier et al., 1993 in view of Kirk et al., 1999 and Easton et al., 1997 for those reasons of record in section 4 of Paper No. 19.

Applicant traverses the rejection on the premises that "the references cited in support of the 35 U.S.C. § 103 rejection do not meet [criteria for obviousness], and that consequently the Examiner has not established a *prima facie* case of obviousness" (last sentence on page 2 of the Response). Applicant submits that "there is no suggestion or motivation in the references themselves or in the knowledge generally available to one of ordinary skill in the art at the time of invention, to modify Stier *et al.* or combine Stier *et al.* with Kirk *et al.* or Easton *et al.* to arrive at the claimed methodology" (beginning at page 3 of the Response). The major disagreement appears to be that the references cited

contain no suggestion or motivation "to arrive at a method for preventing damage to the excitable cells that express a transient K^+ current in a patient who has undergone or is undergoing an ischemic event by administration of an agiotensin II receptor antagonist which increases a transient K^+ current in said cells" (bottom at page 3). These arguments have been fully considered but are not deemed to be persuasive for the following reasons,

Claims 1-7 and 18-20 are directed to a method of preventing damage to the excitable cells of a patient by administration of an effective amount of an angiotensin-II receptor antagonist during or after said patient undergoes or has undergone an ischemic event. Stier et al. describe administration of an angiotensin-II receptor antagonist losartan before stroke but not during or after the stroke, using stroke-prone spontaneously hypertensive rats. Art also discloses therapeutic use of angiotensin-II receptor antagonists for treatment of hypertension (Kirk et al.) and that hypertension is known to be one of the causes of the stroke (Easton et al.). If publication of Stier et al. described administration of losartan during or after stroke, the instant rejection would have been made under 35 U.S.C. § 102, as being anticipatory. In the instant case, because angiotensin-II receptor antagonists are known to be used for the treatment of hypertension, and hypertension is one of the factors that leads to stroke, it would have been *prima facie* obvious to a person of ordinary skill in the art not to discontinue the treatment of a hypertensive patient who undergoes an ischemic event with angiotensin-II receptor antagonist. One of ordinary skill in the art would be motivated to do this because it is obvious that the stroke patient still will be in need of medication to lower the blood pressure, such medication as losartan or saralasin, and further, because the art clearly recognizes the beneficial action

of angiotensin-II receptor antagonists to prevent cerebrovascular ischemia, as disclosed in Stier et al..

Applicant's argument that "in fact such treatment [lowering blood pressure in a patient suffering from stroke] is contradicted in the cited prior art: "Elevated blood pressure should not be lowered unless there is malignant hypertension", Easton et al. (page 4 of the Response) appears to question the enablement of the claimed invention. Because losartan is a drug to lower blood pressure, and, further, because the art teaches not to lower it during the stroke, it appears that losartan cannot be used during stroke at all. However, to reply to Applicant's argument, the cited art (Easton et al.) clearly states that elevated blood pressure should not be lowered during the stroke, which does not necessarily mean the recommendation to discontinue anti-hypertensive medication as soon as a hypertensive patient undergoes a stroke. According to general knowledge in the art, abrupt termination of medication to control the blood pressure could itself lead to lethal consequences. If Applicant is aware of any art that suggest that treatment of hypertension should be discontinued as soon as a patient undergoes an ischemic event, it is suggested that Applicant makes that art of record.

The Examiner maintains the position that because losartan is a drug to treat hypertension, and because Stier et al. disclose beneficial effect of losartan to prevent stroke, at the time the invention was made, it would have been *prima facie* obvious for one of ordinary skill in the art to continue losartan treatment during stroke. Furthermore, the Examiner maintains that administration of an angiotensin-II receptor antagonist, such as losartan or saralasin, would increase a transient potassium current in excitable cells of a patient for those reasons of record fully explained in section 4 of Paper No 19.

Applicant argues that "the Examiner has not shown that the allegedly inherent characteristic of increasins a transient K^+ current in excitable cells by treating hypertension with an angiotensin II receptor antagonist necessarily flows from the applied prior art. In fact, applied prior art teaches that the anti-hypertensive action of Losartan is independent of certain other actions" (bottom at page 6 of the Response) and refers to MPEP § 2112. However, MPEP § 2112 clearly states

SOMETHING WHICH IS OLD DOES NOT BECOME PATENTABLE UPON THE DISCOVERY OF A NEW PROPERTY

The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Applicant's reliance on *Ex parte Levy* is misplaced. In *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) the court held that "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." Id. at 1462 (emphasis in original). The

examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.). In the instant case, the situation disclosed in prior art (administration of losartan) is identical to the one disclosed in the instant specification (administration of losartan). The results of the same procedure are expected to be the same. Thus, one would reasonably conclude that administration of losartan, as disclosed by Stier et al., would inherently protect excitable cells of a patient.

Conclusion

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571)

272-0870. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (571) 273-0870. Official papers should NOT be faxed to (571) 273-0870.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Olga N. Chernyshev, Ph.D. OC

JOHN ULM
PRIMARY EXAMINER
GROUP 1800